PATENT
Customer No. 22,852
Attorney Docket No. 08647.0001

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:	)	
	)	
Joseph P. STEINER *et al.*	)	Group Art Unit: 1627
	)	
Serial No.: 09/873,298	)	Examiner: Bennett M. Celsa
	)	
Filed: June 5, 2001	)	
	)	
For: ROTAMASE ENZYME ACTIVITY INHIBITORS	)	**HAND DELIVER TO GROUP 1627 EXAMINER BENNETT M. CELSA**

10-1-02

Commissioner for Patents
Washington, D.C. 20231

Sir:

COURTESY COPIES

Please **hand deliver** the attached courtesy copies of the Request Under 37 C.F.R. § 1.607 That an Interference Be Declared and Exhibits A through J filed, which were originally filed on April 19, 2002 December 21, 2001, and the Postcard acknowledging the receipt of same by the U.S. Patent and Trademark Office to Examiner Bennett M. Celsa.

Respectfully submitted,

FINNEGAN, HENDERSON, FARABOW, GARRETT & DUNNER, L.L.P.

By: _____
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Date: September 26, 2002

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For: ROTAMASE ENZYME ACTIVITY INHIBITORS	)	**HAND CARRY TO EXAMINER CECILIA J. TSANG**

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Commissioner for Patents
Washington, DC 20231

Sir:

REQUEST UNDER 37 C.F.R. § 1.607
THAT AN INTERFERENCE BE DECLARED

Applicants submit this request pursuant to 37 C.F.R. § 1.607 to provoke an interference with U.S. Patent No. 6,124,328 to Armistead *et al.* ("the '328 patent") (attached as Exhibit A), which issued September 26, 2000, and is assigned on its face to Vertex Pharmaceuticals Inc. Because an interference with an issued patent is requested, Applicants respectfully request that examination of the present application be expedited.

I. AN INTERFERENCE SHOULD BE DECLARED

At the time this application was filed, June 5, 2001, Applicants, in compliance with the requirements of 37 C.F.R. § 1.607(c), informed the Office that claims 1-49 of this application were believed to correspond substantially to at least claims 3, 4, and/or 12 of the '328 patent. Upon entry of the Preliminary Amendment filed concurrently

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herewith, the pending claims are believed to correspond substantially to at least claim 4 and/or 12 of the '328 patent. More precisely, at least one of claims 1-7, 11-15, 25-29, 33-37, 41-45, and 49 of the present application defines the same patentable invention as at least one of claims 4 and/or 12 of the '328 patent. As Applicants demonstrate below, at least one of claims 1-7, 11-15, 25-29, 33-37, 41-45, and 49 of the present application defines allowable subject matter that interferes with the invention claimed in at least one of claims 4 and/or 12 of the '328 patent.

An interference is appropriate between an application and an unexpired patent owned by a different party when the application and the patent contain claims to the same patentable invention. 37 C.F.R. § 1.601(i). The test for ascertaining whether claims are directed to the same patentable invention is set forth in 37 C.F.R. § 1.601(n) as follows:

> Invention "A" is the same patentable invention as an invention "B" when invention "A" is the same as (35 U.S.C. 102) or is obvious (35 U.S.C. 103) in view of invention "B," assuming invention "B" is prior art with respect to invention "A."

Under this test, at least claims 36 and 44 of the present application are directed to the same patentable invention as claim 4 of the '328 patent, as exemplified in the side-by-side comparison for claim 44 of the present application and claim 4 of the '328 patent in Exhibits B1 and B2.[1] The extensive overlap between these claims evident

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[1] Claim 4 of the '328 patent contains an exclusionary proviso, which limits the definition of functional group "B" of the compounds encompassed by that claim depending on the identity of functional group "D" of those compounds. To facilitate a comparison of claim 44 of the present application, which does not contain an exclusionary proviso, with claim 4 of the '328 patent, Exhibit B1 presents that comparison with "D" defined as broadly as possible by claim 4 (*i.e.*, "B" is narrowed by the proviso) and Exhibit B2 presents that

from Exhibits B1 and B2 clearly shows that the invention as defined by claim 4 of the '328 patent (invention "A") anticipates Applicants' invention as defined by claim 44 ("invention "B"). Analogously, Applicants' invention as defined by claim 44 (invention "B") anticipates the '328 patent's invention, as defined by claim 4 (invention "A"). Thus, the invention defined by claim 4 of the '328 patent (invention "A") is the same as the invention defined by Applicants' claim 44 (invention "B"). Furthermore, the comparison set forth in Exhibits B1 and B2, and summarized above, demonstrates that a two-way test for patentability is satisfied in this case.

Although the language of pending claim 44 differs somewhat from that of claim 4 of the '328 patent, one of ordinary skill in the relevant art readily understands that these are semantic differences only. For example, while pending claim 44 recites a "compound having an affinity for FKPB-type immunophilins," claim 4 of the '328 patent recites "a compound with affinity for FKBP12." One of ordinary skill in the art would know that FKBP12 is an FKBP-type immunophilin. *See* '328 Patent, col. 1, lines 24-26 ("Of particular interest is the 12 kDa immunophilin, FK-506 binding protein (FKBP12)"). Similarly, pending claim 44 of the present application recites the step of "administering to said nerve cell an effective amount," while the first step of claim 4 of the '328 patent is "contacting said nerve cells with a composition comprising a neurotrophic amount." Again, the skilled artisan would understand that the meaning of these two phrases is identical since "an effective amount" of a compound for stimulating neurite outgrowth

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comparison with "B" defined as broadly as possible by claim 4 (*i.e.*, "D" is narrowed by the proviso).

(pending claim 44) is a neurotrophic amount ('328 patent claim 4) of that compound.[2]

It also would be evident to one of ordinary skill in the art that claim 36 of the pending application is encompassed by both claim 44 of the pending application and by claim 4 of the '328 patent, as well as patentably indistinct from both of these claims. Claim 36 is drawn to "[a] method for stimulating the growth of at least one damaged peripheral nerve." The skilled artisan would recognize that the method of pending claim 36 is encompassed within the broader method of "stimulating neurite outgrowth by/in a nerve cell" of pending claim 44 and '328 patent claim 4.

Additionally, although claims 1-7, 25, 27-29, 33, 35, 37, 41, 43, 45, and 49 of the present application and claim 12 of the '328 patent are of a different scope than pending claims 36 and 44 and claim 4 of the '328 patent and/or do not literally recite "[a] method for stimulating neurite outgrowth," one of ordinary skill in the art would understand that these claims are drawn to substantially the same subject matter as pending claims 36 and 44, and are patentably indistinct therefrom. For example, pending claims 1-7 are drawn to "[a] method of treating a neurological activity" and pending claims 25 and 27-29 are drawn to "[a] method for promoting neuronal regeneration." One of ordinary skill in the art, however, would recognize that all of these methods as disclosed in the present application, in fact, are methods for stimulating neurite outgrowth by a nerve cell under specific circumstances. Accordingly, the side-by-side comparison of claim 44 of the present application and claim 4 of the '328 patent set forth in Exhibits B1 and B2

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[2] For example, see Examples 2 and 3 of the '328 patent which teach that the neurotrophic activity of the FKBP12 binding compounds utilized in the invention may be determined by measuring neurite outgrowth in PC12 cells or dorsal root ganglion cell cultures.

makes it readily apparent that these claims are directed to the same invention, *i.e.*, they define interfering subject matter, and should be designated as corresponding to the same interference count. 37 C.F.R. § 1.606.

For these reasons, the PTO should declare an interference between the present application and the '328 patent and, in particular, between the invention of pending claims 36 and 44 and claim 4 of the '328 patent.

II. PROPOSED COUNT

Applicants have provided a proposed count pursuant to 37 C.F.R. § 1.601(f) in attached Exhibit C. The proposed count is an alternative style count, which includes the text of independent claim 4 of the '328 patent "or" of dependent claim 44 of the present application. The limitations from independent claim 41 and from dependent claim 43 of the present application, which are implicit in claim 44 by virtue of its recited dependency on claim 43, and ultimate dependency on claim 41, are included in the proposed count for completeness. The proposed count meets the requirement that it not be narrower in scope than any patent claim designated to correspond to the count.

III. CLAIMS CORRESPONDING TO THE PROPOSED COUNT

A claim should be designated to correspond to the count if, considering the count as prior art, the claim would be unpatentable over the count under 35 U.S.C § 102 or § 103. M.P.E.P. § 2309.02. In this case, assuming that the proposed count of Exhibit C were prior art, claims 1-7, 25, 27-29, 33, 35-37, 41, 43-45, and 49 of this application and claims 4 and 12 of the '328 patent would be unpatentable over the proposed count because these claims would be either anticipated by or rendered obvious by the

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proposed count. That is, because claims 1-7, 25, 27-29, 33, 35-37, 41, 43-45, and 49 of this application and claims 4 and 12 of the '328 patent are all drawn to methods for stimulating neurite outgrowth in a variety of situations using groups of substantially overlapping compounds, none of these claims would be patentable over the proposed count, which is drawn to patentably indistinct subject matter. Therefore, claims 1-7, 25, 27-29, 33, 35-37, 41, 43-45, and 49 of this application and claims 4 and 12 of the '328 patent should be designated to correspond to the proposed count. *See* 37 C.F.R. § 1.606.

IV. APPLICANT'S SPECIFICATION SUPPORTS CLAIMS 1-7, 25, 27-29, 33, 35-37, 41, 43-45, and 49

Because claims 1-7, 25, 27-29, 33, 35-37, 41, 43-45, and 49 were original claims of the as-filed application, those claims are fully supported by that disclosure. 37 C.F.R. § 1.607(a)(5).

V. THE APPLICATION'S EFFECTIVE FILING DATE IS EARLIER THAN THE FILING DATE OF THE '328 PATENT

The present application is a continuation-in-part of U.S. Application Serial No. 08/551,026, filed October 31, 1995, and of U.S. Application Serial No 09/359,351, filed July 21, 1999, which is a continuation of U.S. Application Serial No. 08/693,003, filed August 6, 1996, which is a continuation of U.S. Application Serial No 08/479,436, filed June 7, 1995, now U.S. Patent No. 5,614,547 (Exhibit J, "the '547 patent").

The tables of Exhibits D, E, F, G, and H demonstrate that Applicants' earliest-filed U.S. Application Serial No 08/479,436 ("the '436 application", Exhibit I), which was

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08/693,003, filed August 6, 1996, which is a continuation of the '436 application. Thus, a series of copending continuation applications, each of which encompasses the disclosure of the '436 application and is entitled, under 35 U.S.C. § 120, to the June 7, 1995, filing date of the '436 application, directly links the instant application to the '436 application. As shown in Exhibits D, E, F, G, and H for the '436 application, each application in the chain enables one skilled in the art to make and use at least 5 embodiments encompassed by pending claim 44 and by the proposed count. For this reason, the present application is entitled to benefit of the filing date of June 7, 1995, for priority purposes. *Kawai v. Metlesics*, 178 U.S.P.Q. 158, 163 (C.C.P.A. 1973).

VI. THE APPLICATION CLAIMS CORRESPONDING TO THE COUNT ARE PATENTABLE

Since application claims 1-7, 25, 27-29, 33, 35-37, 41, 43-45, and 49 are directed to the same patentable invention as claims 4 and 12 of the '328 patent, these application claims are allowable over the prior art for at least the same reasons that the U.S. Patent and Trademark Office found the claims of the '328 patent to be allowable over the prior art. The relevant substantive distinction between claims 1-7, 25, 27-29, 33, 35-37, 41, 43-45, and 49 of the instant application and claims 4 and 12 of the '328 patent is the presence of an exclusionary proviso in claim 4 of the '328 patent. That proviso excludes a limited number of compounds from the genus recited by claim 4 of the '328 patent. These excluded compounds themselves are encompassed by the claims of Applicants' U.S. Patent No. 5,614,547, to which a claim for priority in the present application has been made. *See Section V, supra.* In this regard, Applicants direct the Examiner to M.P.E.P. § 2307.02, which requires the Group Director's

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approval to issue a rejection of claims on grounds that would also be applicable to patented claims. Applicants are aware of no reason that would render unpatentable the pending method claims encompassing the use of the compounds excluded by the proviso in claim 4 of the '328 patent.

VII. RELEVANT DATES

As demonstrated above and by Exhibits D, E, F, G, and H, this application is entitled to the benefit of the filing date of U.S. Application Serial No 08/479,436, which was filed June 7, 1995. Thus, the effective filing date of the present application is June 7, 1995.

The '328 patent issued from U.S. Application No. 08/795,956 ("the '956 application"), filed February 28, 1997, which was a division of Application No. 08/486,004, filed June 8, 1995. Accordingly, the earliest effective filing to which the '328 patent may be entitled is June 8, 1995.

Based on these relative dates, even if the '328 patent claims are supported by the '956 application, an issue that Applicants do not concede, Applicants' effective filing date of June 7, 1995, is before the '328 patent's effective filing date of June 8, 1995. Consequently, Applicants should be designated as the senior party in an interference on the proposed count.

VIII. THE REQUIREMENTS OF 35 U.S.C. § 135(b) ARE SATISFIED

In compliance with 35 U.S.C. § 135(b), Applicants claimed the same or substantially the same subject matter as the claims of the '328 patent within less than one year after that patent issued. Specifically, in order to provoke an interference,

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Applicants filed original claims 1-49 of the present application on June 5, 2001. This date is less than one year after the '328 patent issued on September 26, 2000. Further, as shown in Exhibit B, claims 1-7, 25, 27-29, 33, 35-37, 41, 43-45, and 49 are drawn to the same, or substantially the same, patentable invention as claims 4 and 12 of the '328 patent. Applicants therefore have satisfied the requirements of 35 U.S.C. § 135(b).

IX. CONCLUSION

In view of the foregoing, Applicants submit that pending claims 1-7, 25, 27-29, 33, 35-37, 41, 43-45, and 49 are directed to allowable subject matter that is patentably indistinct from the subject matter of claims 4 and 12 of the '328 patent. Applicants have demonstrated their right to an effective filing date of June 7, 1995, which is earlier than patentee's effective filing date of June 8, 1995. Accordingly, Applicants respectfully request that the PTO declare an interference between the present application and the '328 patent. In declaring the interference, the PTO is requested to define the count as proposed in this Request, designating application claims 1-7, 25, 27-29, 33, 35-37, 41, 43-45, and 49 and claims 4 and 12 of the '328 patent to correspond to the Count. Applicants further request that they be accorded benefit of the effective U.S. filing date of June 7, 1995, and be designated as senior party in the interference. Finally, upon a determination by the Office that an interference should be declared, Applicants respectfully request that the Office issue a Notice suspending prosecution of this application pending declaration of an interference.

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If any fees are due in connection with the filing of this Request for Interference, please charge such fees (or credit overpayment) to Deposit Account No. 06-0916.

Respectfully submitted,

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Dated: April 19, 2002

By: _____
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